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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,326	04/05/2005	Steffen Hasenzahl	39509-213934	4709
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VENABLE LLP P.O. BOX 34385 WASHINGTON, DC 20043-9998				
EXAMINER				
WELTER, RACHAEL E				
ART UNIT		PAPER NUMBER		
1611				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/530,326

Applicant(s)

HASENZAHN ET AL.

Examiner

RACHAEL E. WELTER

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CD/CD)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Acknowledgment & Claim Status

The examiner acknowledges receipt of the Amendments/Remarks filed on 5/5/08. **Claims 1-3 and 5** are pending in this application. Claim 4 stands cancelled.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3 and 5 are rejected under 35 U.S.C. 102(e) as being anticipated by Hasenzahl et al, Publication No. 2002/0197311.

The applied reference has common inventors and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claims 1-3 and 5 are all drawn to a pharmaceutical and cosmetic formulation comprising of hydrophobic highly disperse silicon dioxide with a tamped density of 70-400 g/L and preferably 90-400 g/L. Further limitations to the claims include having a

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BET surface area between 50 and 400 m²/g (claim 2), 0.01-30 wt.% amount of silicon dioxide (claim 3), and a maximum of 3.0 wt.% of water-wettable contents contained within the silicon dioxide.

Hasenzahl et al teach a pharmaceutical and cosmetic formulation containing pyrogenic silicon dioxide with a tamped density of 80-250 g/L, see abstract. In addition, they disclose a BET surface area between 50 and 400 m²/g, see claim 3, and 0.1-10 wt.% of silicon dioxide, see claim 5. The ranges of tamped density, BET surface area, and wt.% are identical or fit within the ranges of those mentioned in claims 1-3.

Although the wt.% of water-wettable contents contained within the silicon dioxide is not specifically taught in Hasenzahl et al, it is inherent. Applicant has not explicitly defined what is meant by "water-wettable" and only listed a simple method of how it was determined in the specification. In Table 6 on pg. 24 of the Applicant's specification, water-wettable (%) contents are listed with specific tamped densities (within the range of 70-400 g/L) using the prescribed method. Thus, because the tamped densities are within the range specified in Hasenzahl et al, it is reasonable to assume that the prior art's maximum wt.% of water-wettable contents is the same. Because the examiner has no access to laboratory equipment, burden is put on the applicant to prove otherwise.

Response to Arguments

Applicant argues that the characteristic "silicon dioxide contains a maximum of 3.0 wt.% of water-wettable contents" is not inherently met since no hydrophobic product is taught. Applicant cites paragraph [0025] of Hasenzahl et al because it mentions the

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use of surface modifying reagents but no detailed description of the process. Applicant argues that the surface modifying reagent concentration appears critical to the outcome and that the claimed invention is prepared with 10% less dimethyldichlorosilane, cited on pg. 24 starting at line 20 of the specification. Applicant believes that the reduced concentration of the surface modifying reagent leads to two to three fold differences in the water-wettable contents (%) values of the formulation. Since Hasenzahl et al only mention the performance of the surface modifying reagent and no specific concentrations of the surface modifying reagent, applicant argues that there is not enough information in the prior art to render the product with the claimed water-wettable contents (%) values. Applicant believes there is no need to establish product differences between the prior art and instant claims.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e. surface modifying reagent concentration) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). In the instant case, applicant is arguing process of making limitations. However, the instant claims are directed to product claims not method claims. The prior art (Hasenzahl et al) does teach a hydrophobic rendered product by means of a surface-modifying reagent (paragraph 0025). Applicant's argument that the use of a surface modifying reagent is given with no detailed description of the process in the prior art is moot because *none of the instant claims* are

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drawn to the process of making the product using a surface-modifying reagent with critical concentration levels.

In addition, applicant failed to distinguish product differences between the prior art and instant claims. The examiner maintains the argument that because the prior art discloses the same silicon dioxide formulation with the same tamped density, it is reasonable to assume that the prior art's maximum wt.% of water-wettable contents is the same.

The examiner points to MPEP 2112.01, which states:

Products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658.

In addition, MPEP 2112.01 states:

When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Therefore, without evidence that the prior art does not have a maximum of 3.0 wt.% water-wettable contents, it is the examiner's position that the prior art has a similar maximum wt.% of water-wettable contents.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims refer to "hydrophobic highly disperse silicon dioxide." The specification does not provide a definition for the limitation "highly," which is a relative term. Absent a definition and/or further guidance, this limitation renders the claims indefinite for the following reason:

- a.) The extent of dispersion is unclear (eg. granules, dust).
- b.) An upper/lower boundary for what is acceptably "highly disperse" cannot be determined.

Thus, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

In addition, claims 1-3 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the term "DIN 55943." Absent a definition and/or further guidance, this limitation renders the claims indefinite for the following reason:

- a.) A means by which the density is determined in accordance with the standard is not understood.
- b.) The standard could be potentially mutable under different conditions.

Thus, the specification does not provide a standard for ascertaining the term, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Response to Arguments

Applicant argues that "highly disperse" is a term that appears to be accepted in the art and cites US Patent No. 4,298,387. In addition, applicant believes that "tamped density" is a common property and can be measured in a variety of fashions. Applicant argues that the preferred technique of measuring tamped density was indicated.

In response to applicant's arguments surrounding the term "highly disperse," no upper/lower boundary can be determined from the term. In light of the above reference (US Patent No. 4,298,387), the examiner cannot determine the extent of dispersion or the upper/lower boundary for what is acceptably "highly disperse." Absent further guidance or a definition, the rejection is still maintained.

In response to applicant's arguments surrounding the term "DIN 55943," applicant's specification provides no evidence on how the density was determined using the standard. The specification just merely cites that the density was in accordance with this standard and no further explanation is given. Furthermore, the standard could be mutable under different conditions, which the specification fails to distinctly point out. Absent further guidance or definition, the rejection is still maintained.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RACHAEL E. WELTER whose telephone number is (571) 270-5237. The examiner can normally be reached 7:30-5:00 Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached at (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

REW

/Sharmila Gollamudi Landau/
Primary Examiner, Art Unit 1611